MAY 1 6 2002

K021382

3. 510(k) Summary:

Submitter	Synthes (USA) 1690 Russell Road Paoli, PA 19301
Company Contact	Bonnie Smith (610) 647-9700
Name of the Device	Synthes Automated Tack Driver (An accessory to Synthes Resorbable Tack System)
Predicate Device	Synthes Resorbable Tack System, Self-Retaining Tack Driver - K000560
Device Description	Synthes Automated Tack Driver is designed for use with Synthes Resorbable Tacks. Resorbable Tacks provide fixation and aid in the alignment and stabilization of craniofacial bones when used in conjunction with Resorbable Fixation System plates and meshes. To facilitate tack insertion into a predrilled hole in bone, the Self-Retaining Tack Driver previously cleared has been modified for more controlled and repeatable insertion force. A compression spring has been added to the design, which upon release allows automatic tack insertion into a pre-drilled hole in bone.
Intended Use	Synthes Resorbable Tack System is intended for fractures of the craniofacial skeleton including, but not limited to, comminuted fractures of the naso-ethmoidal and infraorbital areas, comminuted fractures of the frontal sinus wall, and midfacial fractures; and reconstructive procedures of the midface or craniofacial skeleton. Synthes Resorbable Tack System is not intended for use in the mandible or other full load-bearing situations, for areas with active infection or for patient conditions including blood supply. limitations, insufficient quantity or quality of bone, or latent infections.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 16 2002

Ms. Bonnie J. Smith
Senior Regulatory Affairs Associate
Synthes (USA)
1690 Russell Road
P. O. Box 1766
Paoli, Pennsylvania 19301

Re: K021382
Trade/Device Name: Synthes (USA) Automated Tack Driver
Regulation Number: 872.4760 and 882.5330
Regulation Name: Bone Plate and Preformed Nonalterable Cranioplasty Plate
Regulatory Class: II
Product Code: JEY and GXN
Dated: April 30, 2002
Received: May 2, 2002

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other

requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K021382

2. Indications for Use

Special 510(k) Device Modification

INTENDED USE STATEMENT

510(k) Number (if known): K021382

Device Name: Synthes Automated Tack Driver
(An accessory to Synthes Resorbable Tack System)

Indications

Synthes Resorbable Tack System is intended for fractures of the craniofacial skeleton including, but not limited to, comminuted fractures of the naso-ethmoidal and infraorbital areas, comminuted fractures of the frontal sinus wall, and midfacial fractures; and reconstructive procedures of the midface or craniofacial skeleton.

Synthes Resorbable Tack System is not intended for use in the mandible or other full load-bearing situations, for areas with active infection or for patient conditions including blood supply limitations, insufficient quantity or quality of bone, or latent infections.

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K021382

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)